K033938

JAN 2 9 2004

510(k) SUMMARY
Kuraray Medical Inc.
CLEARFIL PROTECT BOND

Name of Device

Trade or Proprietary Name:	CLEARFIL PROTECT BOND
Common Name:	resin-based dental adhesive system
Classification Name:	resin tooth bonding agent
Product Code:	76KLE

Preparation Date

December 11, 2003

510(k) Sponsor

Kuraray Medical Inc.
1621 Sakazu, Kurashiki,
Okayama 710-8622
Japan

510(k) Sponsor Contact

Mr. Koji Nishida
Kuraray America, Inc.
101 East 52nd Street
26th Floor
New York, NY 10022
Phone: 800-879-1676
Fax: 888-700-5200

Intended Use

CLEARFIL PROTECT BOND is a resin-based dental adhesive system. The device includes the antibacterial ingredient, 12-methacryloyloxydodecylpyridinium bromide (MDPB), as fully disclosed in the original filing for the device K#023842 (under the name CLEARFIL SE BOND PLUS). No changes are being made to the composition of the device. The only purpose of this 510(k) filing is to add the claim that the device also has an "antibacterial cavity cleansing effect."

Technological Characteristics and Substantial Equivalence

CLEARFIL PROTECT BOND is a resin-based dental adhesive system. The device includes the new antibacterial ingredient 12-methacryloyloxydodecylpyridinium bromide (MDPB), as fully disclosed in the original filing for the device K#023842 (under the name CLEARFIL SE BOND PLUS). No changes are being made to the composition of the device. The only purpose of this 510(k) filing is to add the claim that the device also has an "antibacterial cavity cleansing effect."

Substantial safety and efficacy testing has been conducted on the device, and specifically of the ingredient MDPB. Testing shows MDPB to be biocompatible, and also an effective antibacterial cavity cleanser compared to control groups of dental resin material without MDPB.

CLEARFIL PROTECT BOND is substantially equivalent for purposes of FDA market authorization to Pulpdent Cavity Cleanser (K#974202), Bisco Cavity Cleanser (K#915668), Den-Mat Cavity Cleanser (K#832497), and Ultradent Consepsis Cavity Varnish (K#925375 and K#924982). Although the CLEARFIL PROTECT BOND device has a different antibacterial ingredient (MDPB), the biocompatibility studies submitted with K#023842 demonstrate the safety of MDPB, and the efficacy studies submitted herewith demonstrate its effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 2 9 2004

Kuraray Medical, Incorporated
C/O Mr. Keith A. Barritt, Esq.
Attorney
Fish & Richardson P.C.
1425 K Street, N.W.
Washington, District of Columbia 20005

Re: K033938
Trade/Device Name: CLEARFIL PROTECT BOND
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Codes: KLE and LBH
Dated: December 18, 2003
Received: December 22, 2003

Dear Mr. Barritt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

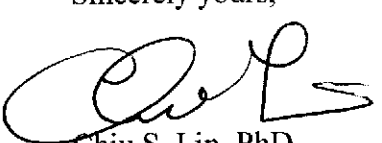
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K033938

Device Name: CLEARFIL PROTECT BOND

Indications For Use:

The CLEARFIL PROTECT BOND device is indicated for the following applications:

1) direct restorations using light-cured composite resin or compomer
2) cavity sealing as a pretreatment for indirect restorations
3) treatment of hypersensitive and/or exposed root surfaces
4) intraoral repairs of fractured crowns/bridges made of porcelain, hybrid ceramics, or composite resin using light-cured composite resin
5) surface treatment of prosthetic appliances made of porcelain, hybrid ceramics, or cured composite resin
6) core build-ups using light- or dual-cured composite resin
7) cavity sealing under amalgam restorations

** For indications 1, 2, 3, 6, and 7 the device exhibits an antibacterial cavity cleansing effect.

(DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____

(Per 21 CFR 801.109)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K033938